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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,497	02/11/2002	Kenneth B. Kirby	2237.006	8128

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/14/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,497

Applicant(s)

KIRBY ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-38 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants, election, filed 07/28/2003.

Response to Election/Restrictions

1. Applicant's election with traverse of Group II, claims 39-40 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the composition of Group I, the method of Group II and the method of Group III are related because each group of claims requires a particular parameter to be present. This is not found persuasive because the composition of Group I can be produced by any other conventional process that does not require the specific steps of quantifying the molecular properties that are required by the process of Group II or III. The process of Group III for selecting the ingredients and amounts of a TDS is not necessary used for making a transdermal delivery system as required by the method of Group II. The method of Group III is only method of selecting the drug and the solvent and their amounts that is distinct from the method of making a TDS as claimed in Group II. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present three distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

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2. Claims 1-38, 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups I and III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Examples of some errors: page 19, line 3: "non-aqueous water" which is missing ",", after aqueous; claim 1: "the term "soluent".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re*

Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the relative skill of those in the art; (5) the amount of direction or guidance presented; (6) the predictability or unpredictability of the art; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The Nature of the Invention: The claims are drawn to the methods of making a transdermal delivery system (TDS) comprises the steps of determining the amount of active agents and solvents that have particular molecular properties; quantifying said molecular properties; and comparing said molecular properties. The molecular properties are specific for each drug and each solvent and the specification does not provide specific drugs and their solubility in specific solvents to enable practicing the method of this invention. The specification also does not provide method of quantifying the molecular properties or method of comparing the molecular properties. The nature of the invention is complex in that it encompasses multiple solvents and wide varieties of active agents that can be used in the instant method.

(2) The Breadth of Claims: The complex nature of the claims is exacerbated by the breadth of the claims. The claims encompass wide varieties of solvent and active agents that are disclosed in page 9, lines 17-22 of the present specification including drugs, medicines, pharmacological, other biologically active ingredients, cosmetically active substances, nutrient substances and the like. This may or may not be addressed

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by the method of the present invention because no disclosure of the solubility of different active agents in different solvents, and the solvent that dissolve one drug may not dissolve the nutrient substance and the like or the biologically active ingredient, absence disclosure of the nature of these substances.

(3) The State of the Art: The state of the art recognized dissolving particular drug in particular solvent. The state of the art does not recognize quantifying the molecular properties and comparing them. Some drugs are water-soluble and others are not or lipid soluble. Determination of the amount of the drug and solvent is very specific for each drug. US 6,019,997 teaches a method of making a transdermal delivery composition comprising mixing the active agent with the emulsifier system to enhance the skin permeation.

(4) The Relative Skill of Those in the Art: The relative skill of those in the art is high.

(5) The Amount of Guidance of the Specification: The guidance given by the specification on the steps of quantifying and comparing the molecular properties as well as the nature of the active agents are lacking.

(6) The Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to determination of the amount of the active agent that can differ from medicine to nutrients to biologically active ingredient, quantification of the molecular properties and comparison of the molecular properties of the active agent and solvent makes practicing the claimed invention unpredictable.

(7) The Presence or Absence of Working Examples: The specification lacks working examples to show how the determination of the dose of active agent and the solvent is carried out, how the quantification of the molecular properties are performed or how the comparison step of the molecular properties is practiced.

(8) The Amount of Experimentation Necessary: The art demonstrates method of making the TDS using particular solvents to particular active agents. Therefore, the practitioner would turn to trial and error experimentation to practice the instant method of making a TDS, without guidance from the specification or the prior art regarding the method of quantifying and comparing the molecular properties. Therefore, undue experimentation becomes the burden of the practitioner.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: making the TDS because the claims are directed to making a TDS but recite only selecting the active agents and the solvent and not the actual making of the TDS.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048.

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The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

ISIS GHALI
PATENT EXAMINER

Is Ghali

10/10/09